

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In Re.:	Patent Application of Bradley J. Eldred	: Group Art Unit 1744 : : :
App. No.:	10/679,660	: Examiner: Monzer R. Chorbaji : :
Filed:	10/6/2003	: : :
Title:	Organic Compound and Metal Ion Synergistic Disinfection and Purification System and Method of Manufacture	: Attorney Docket No. MICROPURE-01 : (066437-5001) : :

**Declaration of Bradley J. Eldred Pursuant to 37 C.F.R. § 1.132**

I hereby declare as follows:

1. I am the same Bradley J. Eldred who is the inventor of the invention described and claimed in the above-identified application.
2. I have read the Office Action dated February 5, 2008, where the Examiner has stated that the Reply filed October 30, 2007 fails to place the application in condition for allowance. Claims 67-74 were rejected as unpatentable under 35 U.S.C. § 103(a).
3. As set forth below and shown in Exhibits A and B, the Claimed Composition provides a improved disinfectant effect against both bacteria and viruses which is greater than the additive disinfectant effects of the individual components of the Claimed Composition, or other combinations thereof.
4. I have tested the disinfectant effect of the Claimed Composition, defined as a composition containing no more than 0.75 milligrams of copper, 0.0375 milligrams of silver, 110 milligrams of grapefruit seed extract, and 220 milligrams of glycerin dissolved in a liter of water, the individual components of the Claimed Composition, and combinations thereof. For each test of individual components or combination of components, the concentration of each component was at the same concentration as in the Claimed Composition. The levels of *Klebsiella terrigena* (bacteria) and MS2 (virus) in the

seeded water matrices were measured initially, and then after various contact times. Tests were conducted using seeded (i.e. spiked with known concentrations of bacteria or viruses) Municipal Water and River Water. Testing was performed by an environmental microbiology laboratory certified as an approved lab under the United States Environmental Protection Agency's (USEPA) National Environmental Laboratory Accreditation Program (NELAP). The testing laboratory is also approved by the USEPA for providing microbiological analyses compliant with the USEPA's LT2 Rule. The following components and combinations thereof were tested in at least one type of water and with at least one microbe type:

- (a) Silver ions
- (b) Copper ions
- (c) Grapefruit seed extract
- (d) Glycerin
- (e) Silver and copper ions
- (f) Grapefruit seed extract with glycerin
- (g) Grapefruit seed extract with deionized water
- (h) Copper ions, silver ions, and glycerin
- (i) Copper ions, silver ions, grapefruit seed extract and deionized water
- (i) Copper ions, silver ions, grapefruit seed extract, and glycerin (Claimed Composition).

5. The bacteria levels were measured as Colony Forming Units per milliliter (CFU/ml). The virus levels were measured as Plaque Forming Units per ml (PFU/ml). These quantitative measurement units are used for determining the concentration of bacteria and viruses in various matrices and are the world-wide standard metric used for measuring in studies assessing both microbe concentrations and disinfection efficacy.

6. Exhibit A, attached hereto, presents the disinfectant effect at various contact times of the Claimed Composition as well as the individual components and various combinations on Municipal Water that was seeded with the standard bacteria and viruses.

Exhibit B, attached hereto, presents similar data for River Water that was seeded with bacteria and with viruses. Municipal Water represents “tap water” – drinking water as delivered by a Public Water Supply entity. River Water represents water that is high in organic and inorganic species, high in turbidity (cloudiness), high in dissolved and suspended solids and with a pH that is typically higher than 7.5.

7. The data presented in Exhibits A and B show the disinfection efficacy of various individual components and combinations of those components at different contact times expressed 1) as the “Log Reduction Value by Contact Time” of the initial counts of the bacteria or virus and 2) in terms of “Improvement Factor.”

8. “Log Reduction Values” presented in Exhibits A and B represent the decrease, in log values to the base 10, of the original bacteria or virus concentration after various contact times with the individual components and combinations of those components. A one log reduction from the initial microbe concentration is equal to a 90% reduction in the initial count of the organism; two logs are equal to a 99% reduction, three logs are equal to a 99.9% reduction, etc. Complete kill (bacteria) or inactivation (viruses) is achieved when the initial concentration of bacteria or virus per mL is reduced to  $<1$  organism per mL (the quantitative detection level limit of the analyses). For instance, if the initial concentration (in CFUs / ml or PFUs / mL) of the bacteria or virus is at 6.00 log, a log reduction of 6.00 after 60 minutes of contact time would represent complete kill / inactivation of the bacteria / virus ( $>99.9999\%$  reduction). Similarly, a 3.00 log reduction at 60 minutes of contact time would represent only a thousand-fold reduction (99.9% reduction). A log reduction of 0.00 means that the component or combination of components being tested was completely ineffective on the target organism. The maximum log reduction for any disinfection efficacy test is, by definition, limited to the challenge level (the starting level) of the organism. Since the challenge level is based on the culture of live bacteria or viruses and since the concentration of the culture can vary from test to test, there is an expected variation in challenge levels shown in Exhibits A and B. As a result, the maximum log reduction levels possible varies somewhat between the tests reported in those exhibits.

9. Improvement Factor values presented in Exhibits A and B use the Log Reduction Value disinfection efficacy of the Claimed Composition after a 60 minute contact time as a benchmark value and provide quantitative comparisons of the disinfection efficacies after 60 minutes of contact time for the individual components or combinations of components compared to the Claimed Composition. Data presented under Improvement Factor show the superiority of the Claimed Composition to its individual components and combinations thereof on achieving kill or inactivation of the target organism. The Improvement Factor is expressed in two different ways for clarity – “Superiority - Log Values” and “Superiority - how many times better.” If an individual component or combination of components was equally as effective as the Claimed Composition, the value (“Superiority - Log Value” or “Superiority - how many times better”) under Improvement Factor would be 0.00 for Log Value or 0 for “how many times better,” meaning that no improvement in disinfectant effect was demonstrated. If the value in Improvement Factor is 3.00 (99.9%) for Log Value or 1000 for “how many times better” (the numbers are equivalent), that would mean that the Claimed Composition was 1000 times more effective than the component or combination of components to which it was being compared. Similarly, an Improvement Factor Log Value of 5.00 (99.999%) or a “how many times better” value of 100,000 would indicate that the Claimed Composition was 100,000 times more effective than the comparative component or combination of components.

10. Any product that does not achieve a viral log reduction that is greater than or equal to 4 logs (99.99%) is not accepted by the United States Environmental Protection Agency (USEPA) and other regulatory bodies’ classification as a “disinfectant.” The bacterial standard is 6 logs.

11. Exhibit A shows that the Claimed Composition demonstrates a marked improvement in disinfection efficacy over the tested individual components and other combination of components on viruses in seeded Municipal Water. Using 60 minutes of contact time as a basis for comparison, the Claimed Composition showed an Improvement Factor that ranged from approximately 275,000 to 27,000,000 times more effective than any individual component or any combination of the individual components of the Claimed Composition in inactivating viruses in Municipal Water. Additionally, Exhibit A shows

that none of the individual components or other combinations of the components achieved more than a 2-log (99%) reduction in viruses in seeded Municipal Water (and therefore could not be classified as a disinfectant by the USEPA), while the Claimed Composition achieved more than a 7-log reduction (>99.9999%) (and adequately meets the 4-log requirement by the USEPA for being classified as a disinfectant).

12. Exhibit A also presents data at the 60 minute contact timepoint showing that the Claimed Composition demonstrates a Improvement Factor that is up to 45,000 times greater than specific individual components or other combinations of components on bacteria in seeded Municipal Water, although, as noted in the original application, silver / copper ions alone were known to be effective in bacterial reduction.

13. Exhibit A presents additional data that further show the superiority of the Claimed Composition for disinfecting bacteria in seeded Municipal Water at a 30 minute contact time. As shown in Exhibit A, only the Claimed Composition achieved a complete kill after a contact time of 30 minutes. While copper and silver were nearly as effective, the Claimed Composition ranged from being about 100 to about 100,000 times as effective as the other components or combinations of components as seen by comparing the log reduction values under the 30 minute contact time column. The Claimed Composition gives a more complete kill and also works more rapidly than its individual components or other combinations of components.

14. Exhibit B includes the viral reduction data at 60 minutes of contact time on seeded River Water. Using this as a basis for comparison, the Claimed Composition showed a disinfection efficacy that ranged from approximately 2,700 to 27,000 times more effective than any individual component or any other combination of the individual components of the Claimed Composition. The viral data presented in Exhibit B also show that none of the individual components or any combination of the components achieved more than a 1-log (90%) reduction in viruses in seeded River Water while the Claimed Composition achieved a 4.4-log reduction (>99.99%).

15. Using comparative results at the 60 minute contact timepoint, the data in Exhibit B also show that the Claimed Composition demonstrates an improved disinfection efficacy

on bacteria in seeded River Water as compared to the individual components and other combinations thereof. The Claimed Composition's disinfection efficacy ranged from a factor of 2 to approximately 800 times that of any individual component or other combination of components.

16. Additionally, the data in Exhibit B shows that the addition of glycerin to a solution of copper and silver ions decreased the disinfection efficacy against viruses in River Water. The addition of glycerin to a solution of copper and silver ions resulted in a decrease of the 60 minute Log Reduction in viruses from 1.12 (for a solution of copper and silver ions) to <1.00 (for a solution of copper and silver ions with glycerin). Similarly, Exhibit A shows that the addition of glycerin to a solution of copper and silver ions decreased the disinfection efficacy against bacteria in Municipal Water. The addition of glycerin to a solution of copper and silver ions resulted in a decrease of the 30 minute Log Reduction in bacteria from 5.57 (for a solution of copper and silver ions) to 3.64 (for a solution of copper and silver ions with glycerin).

17. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

10 JULY 2008  
Date

Bradley J. Eldred  
Bradley J. Eldred

## Municipal Water

### Municipal Water

## River Water

## River Water